# **Safety Devices**

Safe-Mate® Safety Needle
BD Bard-Parker Protected Blade System
Weighted Safety Scalpel
Safety Needles and Intraoral Injections
1SHOT Safety Syringe
Ultra Safety Plus XL Safety Syringe
Evaluation of Safety Scapels
Safety Intravenous (IV) Catheters as an Infection Control Tool

Safe-Mate Safety Needle (5/06) For UPDATE, click here.

**Question:** Has DECS evaluated the Safe-Mate Safety Needle? What are the advantages and disadvantages of this safety device?

Answer: DECS recently completed a clinical-user evaluation of the Safe-Mate Safety Needle manufactured by MedPro Safety Products. Each Safe-Mate safety needle is individually wrapped in sterile packaging. The safety needle attaches on most standard metal aspirating syringes just like an ordinary dental needle. To use a Safe-Mate safety needle, the user simply presses the safety release and slides down the protective sleeve and proceeds with the



injection. After each injection, or to change anesthetic cartridges simply slide the sleeve back over the needle into the locked position. According to MedPro Safety this procedure can be accomplished with one hand. The instructions include an illustrated step-by-step instruction sheet and an instructional CD. The Safe-Mate Safety Needle offers protection from the needle because the needle is covered before the injection and can be easily covered after the injection. Evaluators found the Safe-Mate Safety Needle easy to assemble and reported that the safety feature was easy to recognize and use. Most evaluators reported that the device functioned as intended and was reliable during the evaluation period. There was



one reported percutaneous injury during the evaluation period. This involved a dental assistant who had not received appropriate training on the product and when the needle was being removed from the syringe the protective sleeve was inadvertently activated and the assistant was stuck with the needle. Thirty-eight percent (6/16) of the evaluators experienced difficulty visualizing aspiration of blood into the anesthetic cartridge. When asked to comment on the overall

safety of the device, 10 of 16 dentists agreed that the device was safe, two disagreed, and four were undecided. When asked if the device was safer than using a conventional needle recapped using one hand, eight dentists (50%) agreed with the statement, four (25%) disagreed, four (25%) were undecided. When asked the same question, 39% (4/13) of the dental assistants felt the product was safer than using a conventional needle recapped using one hand and 52% (8/13) did not feel the product was safer. Evaluating safety devices is challenging and several factors can impact the outcome of the product evaluation. With the introduction of any new device or technique, a period of adjustment and relearning of technique is necessary. The short duration of this clinical evaluation; staff experience and preference for

conventional devices; and perceived needs for devices with safety features are factors that can affect safety device evaluation. It is also important to consider that when presented with a device that has a significantly different design than a traditional device, decisions regarding preference and future use can be dependent upon the individual practitioners' style and technique. All of these factors can affect the evaluation of safety devices and could account for the variety of opinions obtained during this evaluation. This illustrates the importance of having staff members responsible for patient care involved in the identification and selection process when considering and evaluating new safety devices.

Manufacturer	MedPro Safety Products, Inc. 817 Winchester Road, Suite 200 Lexington, KY 40505 (800) 511-1669 (859) 225-5375		
	(859) 225-5347 FAX www.safe-mate.com		
Suggested Retail Price	\$32.00 100 individually packaged, sterile Safe-Mate Safety Needles		
Government Price	\$32.00 100 individually packaged, sterile Safe-Mate Safety Needles		
Available Sizes/Product Numbers	Size (color coding)  25 gauge long (red)  27 gauge short (orange)  27 gauge long (yellow)  30 gauge short (blue)  30 gauge extra short (purple)  Product Number  N5252  N5271  N5272  N5301  N5300		
Advantages <sup>1</sup>	+ Potential to decrease percutaneous injuries compared to conventional dental needle + Provides an engineering control making incorrect needle recapping less likely + Can be attached to a conventional metal dental anesthetic syringe + Safety feature can be activated using one hand + Individually wrapped in sterile packaging material		
Disadvantages <sup>1</sup>	<ul> <li>Bulkiness of plastic protective sleeve may reduce visibility in the oral cavity</li> <li>Plastic protective sleeve may fog and reduce visibility in the oral cavity</li> <li>May be difficult to see aspirated blood through the protective sleeve</li> <li>May not fit all conventional metal dental anesthetic syringes</li> <li>More flexible than other dental needles</li> <li>Produces an increased volume of sharps waste</li> <li>Requires a certain period of accommodation by the user</li> </ul>		

<sup>&</sup>lt;sup>1</sup>Information compiled from limited DECS clinical evaluations.

**UPDATE** In October 2008, DECS learned that MedPro Safety Products, Inc. is no longer selling the Safe-Mate® Safety Needle.

## BD Bard-Parker™ Protected Blade System (3/06)

**Question:** I recently saw an advertisement for a safety scalpel that has an autoclavable metal handle and disposable blades with protective coverings. Does DECS have any information about this safety scalpel?

Answer: The scalpel blade is a type of sharp that has been implicated in percutaneous injuries. With a conventional scalpel, injuries can occur when passing the instrument to other dental team members; when removing the contaminated blade from the handle; or when the blade is left uncovered on the instrument tray. The BD Bard-Parker™ Protected Blade System consists of an autoclavable metal scalpel handle designed with the weight and feel comparable to a traditional scalpel. Disposable Protected Blade System Cartridges are attached to the metal handle before use. The cartridge has a protective safety shield over the scalpel blade designed to protect users from accidental percutaneous injuries associated with conventional blades. The safety shield can be extended and retracted using one hand, which can minimize the potential for percutaneous injury. Also, the blade can remain covered during both assembly and disposal to help prevent accidental contact with the blade. The disposable Protected Blade System Cartridges are currently available in a variety of blade sizes (see table below).

DECS recently completed a limited clinical evaluation of the BD Bard-Parker™ Protected Blade System. Ten evaluators (two oral surgeons, four general dentists, and four dental assistants) participated in the clinical evaluation. All evaluators reported that it was easy to remove the device aseptically from the package. The evaluators found the safety feature easy to use and recognize, and reported that it functioned as intended during the evaluation. All evaluators agreed that the weight and size of the device

was acceptable, well balanced, and stable during use. None of the evaluators reported that they changed their technique when using the device. All evaluators agreed that they had good access to all areas of the oral cavity with only one evaluator commenting that the extra material on the cartridge containing the blade made it more difficult to see around. All



agreed that the BD Bard-Parker™ Protected Blade System was safer than a conventional scalpel and that the device could be considered to be interchangeable with a conventional scalpel. There were no reported percutaneous injuries during the evaluation period. Dental assistants appreciated the protective cover over the blade, which made injury less likely and they offered positive comments about the ease of assembly and blade removal from the scalpel handle. Overall the BD Bard-Parker™ Protected Blade System received high ratings during this limited clinical evaluation from both the dentists and the dental assistants.

Evaluating safety devices is challenging and several factors can impact the outcome of the product evaluation. With the introduction of any new device or technique a period of adjustment and relearning of technique is necessary. The short duration of this clinical evaluation; staff experience and preference for conventional devices; and perceived needs for devices with safety features are factors that can affect safety device evaluation. Furthermore, the individual practitioner's style and technique must also be considered when evaluating and choosing devices with a significantly different design than a conventional device. While it is not presently mandatory to use safety scalpels, OSHA requires annual consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure. The BD Bard-Parker™ Protected Blade System was found to be safe for clinical use during this limited evaluation, and is an example of a device that could be evaluated in USAF dental clinics to fulfill the OSHA evaluation requirement.

Manufacturer/Distributor	Manufacturer:			
Manufacture//Distributor				
	Becton, Dickinson and Company			
	1 Becton Drive			
	Franklin Lakes, NJ 07417			
	(888) 237-2762			
	(201) 847-6800			
	(800) 847-2220 FAX			
	www.bd.com			
	Distributor:			
	Crosstex International			
	10 Ranick Road			
	Hauppauge, NY 11788-4209			
	(888) 276-7783			
	(631) 582-6777			
	(631) 582-1726 FAX			
	www.crosstex.com			
Price	Suggested Retail Price:			
	\$175.50 Box of 5 Protected Blade System Handles Size 3*			
	\$175.50 Box of 5 Protected Blade System Handles Size 4 <sup>†</sup>			
	\$268.50 Case of 150 Protected Blade System Cartridges§			
	\$298.50 Case of 150 Protected Blade System Cartridges Size 12			
	\$463.50 Box of 50 Protected Blade System Cartridges Size 12B			
	O			
	Government Price <sup>1</sup> :			
	\$135.45 Box of 5 Protected Blade System Handles Size 3*			
	\$135.45 Box of 5 Protected Blade System Handles Size 4 <sup>†</sup>			
	\$185.76 Case of 150 Protected Blade System Cartridges			
	\$185.76 Case of 150 Protected Blade System Cartridges Size 12			
	\$140.30 Box of 50 Protected Blade System Cartridges Size 12B			
	* For use with blade sizes 10, 11, 15, 10A, 15C			
	† For use with blade sizes 12, 12B, 20-25			
	§ Pricing for frequently used blade sizes 10, 11, and 15			
	Tribing for requestify used blade sizes 15, 11, and 15			
Available Blade Sizes	#s 10, 11, 12, 15, 20, 21, 22, 23, 10A, 12B, 15C			
Summary of Safety Feature	Autoclavable stainless steel handle with disposable Protected Blade System			
	Cartridges. The cartridge has a protective safety shield over the scalpel blade			
	designed to protect users from accidental percutaneous injuries associated with			
	conventional blades. The safety shield can be extended and retracted using one			
	hand.			
Advantages <sup>1</sup>	+ Potentially safer because it may minimize risk for percutaneous injuries			
	+ Potentially safer for patients and staff because the protective safety shield			
	covers the blade until needed and upon blade removal			
	+ Stainless-steel, autoclavable handle with conventional weight and feel			
	+ Easier blade assembly compared to a conventional scalpel			
	+ Easier blade removal compared to a conventional scalpel			
	+ Safety feature can be activated with one hand			
	+ Safety feature is easy to recognize and use			
	+ Protected Blade System Cartridges conveniently packaged			
	+ Provides audible and tactile confirmation of safety feature lock			
Disadvantages <sup>1</sup>	- Handles are not compatible with all blade sizes			
<sup>1</sup> Information compiled from limit	ed DECS clinical evaluations.			

### Sandel Weighted Safety Scalpel™ (10/05)

**Question:** I recently saw an advertisement for a disposable safety scalpel that reportedly has a weight comparable to a conventional scalpel. Does DECS have any information about this scalpel from Sandel Medical Industries?

Answer: The scalpel blade is a type of sharp that has been implicated in percutaneous injuries. With a conventional scalpel, injuries can occur when passing the instrument to other dental team members; when removing the contaminated blade from the handle; or when the blade is left uncovered on the instrument tray. The Sandel Weighted Safety Scalpel™ has a protective safety shield over the scalpel blade designed to protect dental health-care personnel (DHCP) from accidental percutaneous injuries associated with conventional sterilizable scalpel handles and disposable blades. The safety shield can be extended and retracted using one hand which can minimize the potential for percutaneous injury. Also, the blade does not have to be removed from the handle before disposal further enhancing safety by decreasing the risk of percutaneous injury.

DECS recently completed a limited clinical evaluation of the Sandel Weighted Safety Scalpel™. During this clinical evaluation, five evaluators (general dentists, periodontists, and oral surgeons) used the

disposable scalpel for a total of 151 incisions. All evaluators agreed that the instructions were easy to understand, the packaging was convenient, and that it was easy to remove the scalpel aseptically from the package. All evaluators agreed that the weight and size of the device was acceptable and well balanced. Additionally, all agreed that the blade was sharp for the initial incision. Most evaluators (3/5) were



neutral with respect to blade sharpness after the initial incision. The evaluators found the safety feature easy to use and recognize, and reported that it functioned as intended during the evaluation. The main disadvantages noted were the flexibility of the handle/blade connection and size. Several evaluators commented that they would prefer a device with a more rigid handle and blade connection design. Several evaluators commented that they would prefer a slimmer handle design to make the disposable scalpel less bulky and possibly improve access in patients with a small mouth. There were no reported percutaneous injuries during the evaluation period. When the evaluators were asked to comment whether they thought that the device was safer than a conventional scalpel and blade, four evaluators agreed that it was safer and one evaluator was undecided. The five evaluators agreed that the device was safe for clinical use.

Evaluating safety devices is challenging and several factors can impact the outcome of the product evaluation. With the introduction of any new device or technique a period of adjustment and relearning of technique is necessary. The short duration of this clinical evaluation; staff experience and preference for conventional devices; and perceived needs for devices with safety features are factors which can affect safety device evaluation. It's also important to consider that when presented with a device that has a significantly different design than a traditional device, decisions regarding preference and future use can be dependent upon the individual practitioner's style and technique. All of these factors can affect the evaluation of safety devices and could account for the variety of opinions obtained during this evaluation. This illustrates the importance of having staff members responsible for patient care involved in the identification and selection process when considering and evaluating new safety devices.

While it is not presently mandatory to use safety scalpels, OSHA requires annual consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure. The Sandel Weighted Safety Scalpel™ was found to be safe for clinical use during this limited DECS evaluation, and is an example of a device that could be evaluated in USAF dental clinics to fulfill the OSHA evaluation requirement.

Manufacturer	Sandel Medical Industries, LLC				
	9540 De Soto Ave				
	Chatsworth, CA 91311				
	(866) 764-3327				
	(818) 534-2500				
	(818) 534-2510 FAX				
	www.sandelmedical.com				
Price	Suggested Retail Price:				
	\$170.88 Case of 96 Weighted Safety Scalpels™ (silver scalpel)				
	(\$1.85 each)				
	Government Price:				
	\$160.63 Case of 96 Weighted Safety Scalpels™ (silver scalpel)				
	(\$1.67 each)				
Available Blade Sizes	#s 10, 11, 15				
Summary of Safety Feature	Protective safety shield safety shield covers the blade (activated via				
	locking/unlocking button) during periods of nonuse.				
Advantages <sup>1</sup>	+ Potentially safer because it may minimize risk for percutaneous injuries				
	+ Potentially safer for patients and staff because the protective safety				
	shield covers the blade until needed				
	+ Weight comparable to conventional sterilizable scalpel				
	+ Conveniently packaged				
	+ Safety feature is easy to recognize and use				
	+ Safety feature can be activated with one hand				
	+ TIME OUT™ removable sleeve is a reminder to comply with JCAHO's				
	Universal Protocol				
	+ Enhances infection control and safety because of its disposability				
Disadvantages <sup>1</sup>	- Blade/handle connection somewhat more flexible than a conventional				
	device; may make the device feel unstable during use				
	- Handle is thicker than traditional scalpel handle; may make access				
	difficult to all areas of the mouth				

<sup>&</sup>lt;sup>1</sup>Information compiled from limited DECS clinical evaluations.

# **Safety Needles and Intraoral Injections** (9/05)

**Question:** Is it mandatory to use safety needles for intraoral dental injections?

**Answer:** Presently, it is not mandatory to use safety needles when giving intraoral injections. however the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogen Standard (29 CFR 1910.1030) requires the use of engineering and work practice controls (in addition to standard precautions and use of personal protective equipment) to reduce the employee's exposure to bloodborne pathogens. OSHA also requires evaluation of the effectiveness of existing controls and consideration of more advanced engineering controls such as safer needle devices as they become available. Employees directly responsible for patient care (e.g., dentists, hygienists, and dental assistants) should be involved in identifying and choosing these

### **Sharps Safety**

- Do not pass syringes with unsheathed needles.
- Do not recap used needles by using both hands or any other technique that involves directing the point of a needle toward any part of the body.
- Do not bend, break, or remove needles before disposal except to remove needles from non-disposable dental anesthetic syringes.
- Use either a one-handed scoop technique or a mechanical device designed for holding the needle cap when recapping needles.
- Place used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant containers located as close as feasible to the area in which the items are used.

devices.<sup>1</sup> This is important because when presented with a device that has a significantly different design than a traditional device, decisions regarding preference and future use can be dependent upon the individual practitioner's style and technique.

Aspirating anesthetic syringes that incorporate safety features have been developed for dental procedures, but the low injury rates in dentistry limit assessment of their effect on reducing injuries among dental health-care personnel (DHCP).<sup>2</sup> The USAF Dental Evaluation and Consultation Service (DECS) has performed limited clinical evaluations of two currently available dental safety anesthetic syringes. Neither was universally accepted by the evaluators, and it is acceptable to continue to use the conventional dental anesthetic syringe with appropriate work practices such as one-handed recapping (e.g., the scoop technique, using a needle recapping device) and not passing needles unsheathed.

Safer versions of sharp devices used in hospital settings have become available (e.g., blunt suture needles, phlebotomy devices, and butterfly needles), and their impact on reducing injuries has been documented.<sup>3-6</sup> Therefore, if you're doing IV sedations in the dental clinic, you are required to use IV safety equipment. Also, safety scalpels are becoming more widely available and have the potential to decrease percutaneous injuries. DECS has evaluated several safety scalpels.

Additional information on identifying and evaluating safer dental devices in USAF dental facilities is available in the USAF Guidelines for Infection Control in Dentistry and the March 2005 *InControl* Fact Sheet: Evaluating Safety Devices in USAF Dental Clinics.

#### References

- 1. US Department of Labor Occupational Safety and Health Administration 29 CFR Part 1910.1030 Occupational Exposure to Bloodborne Pathogens, Needlestick and Other Sharps Injuries; Final Rule. Federal Register 2001; 66 (12); 5317–5325. As amended from and includes Federal Register 1991 29 CFR Part 1910.1030 Occupational Exposure to Bloodborne Pathogens; Final Rule. 56(235);64174–64182.
- 2. CDC. Guidelines for infection control in dental health-care settings 2003. MMWR 2003; 52(No. RR-17):1–66.
- 3. CDC. Evaluation of safety devices for preventing percutaneous injuries among health-care workers during phlebotomy procedures—Minneapolis-St. Paul, New York City, and San Francisco, 1993–1995. MMWR 1997;46:21–25.

- 4. CDC. Evaluation of blunt suture needles in preventing percutaneous injuries among health-care workers during gynecologic surgical procedures—New York City, March 1993–June 1994. MMWR 1997:46:25–29.
- 5. Mendelson MH, Lin-Chen BY, Solomon R, Bailey E, Kogan G, Goldbold J. Evaluation of a safety resheathable winged steel needle for prevention of percutaneous injuries associated with intravascular-access procedures among healthcare workers. Infect Control Hosp Epidemiol 2003;24:105–112.
  6. CDC. Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program. Available at: <a href="https://www.cdc.gov/sharpssafety/index.html">www.cdc.gov/sharpssafety/index.html</a>. Accessed August 2011.

# **1SHOT™ Safety Syringe** (3/05) For **UPDATE** click here.

**Question:** Has DIS evaluated the 1SHOT™ Safety Syringe? What are the advantages and disadvantages of this safety anesthetic syringe?

**Answer:** The 1SHOT™ Safety Syringe from Sultan Safety, LLC is a sterile, single-use disposable syringe with a protective sheath and a re-usable autoclavable plunger assembly (up to 100 cycles). It is intended



to be used with standard pre-filled 1.8 mL anesthetic carpules and screw-on dental needles (up to 1 3/8" [35 mm] length). The 1SHOT™ Safety Syringe incorporates a needle retraction and readvancing mechanism that can be operated with one hand. The manufacturer claims the syringe is designed to provide significant protection from the needle before, during and after

the injection. The 1SHOT™ Safety Syringe offers protection from the needle because the needle is protected before the injection and can be easily re-sheathed after the injection. Also, the needle does not have to be removed prior to disposal of the protective sheath eliminating exposure of the worker to unnecessary risk. The device allows visualization of the cartridge contents when aspirating and the O-ring plunger allows anesthetic carpules to be changed safely, reducing the possibility of injury inherent in a harpoon plunger. The instructions include an illustrated step-by-step instruction sheet and an instructional CD. Evaluators found the 1SHOT™ Safety Syringe easy to assemble and reported that the safety feature was easy to recognize and use. Most evaluators reported that the device functioned as intended and was reliable during the evaluation period. There were no reported percutaneous injuries during the evaluation period. However, one evaluator commented that increased coordination and finger manipulation were necessary to activate the safety feature and another had difficulty with the locking spring retracting. Most evaluators stated that they had a clear view of the needle tip and injection site and that they would be able to clearly visualize aspiration of blood into the anesthetic cartridge. They also agreed that it was easy

to change anesthetic carpules with only three of eleven evaluators experiencing difficulty. When asked to comment on the overall safety of the device, 10 of 11 evaluators agreed that the device was safe for clinical use and one remained neutral. When asked if the device was safer than using a conventional needle recapped using one hand the results were equivocal with one strongly agreeing with the statement, three agreeing, five disagreeing, and two remaining neutral. Evaluating safety devices is challenging and several factors



can impact the outcome of the product evaluation. With the introduction of any new device or technique, a period of adjustment and relearning of technique is necessary. The short duration of this clinical evaluation; staff experience and preference for conventional devices; and perceived needs for devices

with safety features are factors that can affect safety device evaluation. It's also important to consider that when presented with a device that has a significantly different design than a traditional device, decisions regarding preference and future use can be dependent upon the individual practitioner's style and technique. All of these factors can affect the evaluation of safety devices and could account for the variety of opinions obtained during this evaluation. This illustrates the importance of having staff members responsible for patient care involved in the identification and selection process when considering and evaluating new safety devices.

Manufacturer	Sultan Safety, LLC				
	(A Sultan Chemists, Inc. Company)				
	85 West Forest Avenue				
	Englewood, NJ 07631				
	(800) 637-8582				
	(201) 871-1232				
	(201) 871-0321 FAX				
	www.sultanchemists.com				
Suggested Retail Price	\$440.00 240 (case of 8 boxes) 1SHOT™ Safety Syringes & 1 Autoclavable				
	Plunger				
	\$600.00 400 (case of 4 boxes) 1SHOT™ Safety Syringes & 1 Autoclavable				
	Plunger				
	\$250.00 30 – Autoclavable Plungers				
Government Price	\$264.00 240 (case of 8 boxes) 1SHOT™ Safety Syringes & 1 Autoclavable				
	Plunger				
	\$360.00 400 (case of 4 boxes) 1SHOT™ Safety Syringes & 1 Autoclavable				
	Plunger				
	\$150.00 30 – Autoclavable Plungers				
Advantages <sup>1</sup>	+ Potential to decrease percutaneous injuries compared to conventional				
	syringe system				
	+ Provides an engineering control making incorrect needle recapping less				
	likely + Safe and easy breakdown and insertion into sharps container + Safety feature can be activated using one hand + Easy to see aspirated blood through translucent body assembly + Visibility of the needle and carpule contents is not obstructed during use + Adaptable to any hand size				
	+ Adaptable to any hand size + Ability to change anesthetic carpules efficiently				
	+ Uses standard dental needles				
	+ Disposable and lightweight				
Disadvantages <sup>1</sup>	- Produces increased volume of sharps waste				
2.5davarilagoo	- Difficult to keep track of how many times the plunger has been sterilized				
	- Requires a certain period of accommodation by the user				
	- More expensive than a conventional syringe system				
	I Moro expensive than a conventional syninge system				

<sup>&</sup>lt;sup>1</sup>Information compiled from limited DIS clinical evaluations.

**UPDATE** In May 2005, Sultan Chemists informed DECS that they are no longer selling the 1 SHOT™ Safety Syringe. The discontinuation is the result of a recent strategic business decision. The safety syringe is available for sale through Med Design Corporation. For more information please contact:

Med Design Corporation 2810 Bunsen Avenue Ventura, CA 93003 (805) 339-0375 (805) 339-9757 FAX www.med-design.com

**UPDATE** In October 2006, DECS learned that Med Design Corporation is no longer selling the 1 SHOT™ Safety Syringe.

# **Ultra Safety Plus XL Safety Syringe (2/05)**

**Question:** Has DIS evaluated the Ultra Safety Plus XL Safety Syringe? What are the advantages and disadvantages of this safety syringe?

Answer: DIS recently completed a clinical-user evaluation of Septodont's Ultra Safety Plus XL Safety Syringe. The sterile disposable protective sheath is fitted with a dental needle and it accepts standard anesthetic carpules. The reusable plunger assembly is autoclavable. The instructions include an illustrated step-by-step instruction sheet and an instructional CD. The Ultra Safety Plus XL Safety Syringe offers protection from the needle because the needle is protected before the injection and can be easily re-sheathed after the injection. Also, the needle does not have to be removed prior to disposal of the protective sheath eliminating exposure of the worker to unnecessary risk. Evaluators found the Ultra Safety Plus XL easy to assemble and reported that the safety feature was easy to recognize and use. Most evaluators reported that the device functioned as intended and was reliable during the evaluation period. There were no reported percutaneous injuries during the evaluation period. However, evaluators

found it difficult and more time consuming to change anesthetic carpules compared to a conventional syringe. Fifty percent of 10 evaluators experienced difficulty visualizing aspiration of blood into the anesthetic cartridge. When asked to comment on the overall safety of the device, the results were equivocal with five agreeing that the device was safe, three disagreeing, and two



remaining neutral. When asked if the device was safer than using a conventional needle recapped using one hand, four agreed with the statement, four disagreed, one was neutral, and one did not reply. Evaluating safety devices is challenging and several factors can impact the outcome of the product evaluation. With the introduction of any new device or technique, a period of adjustment and relearning of technique is necessary. The short duration of this clinical evaluation; staff experience and preference for conventional devices; and perceived needs for devices with safety features are factors that can affect safety device evaluation. It's also important to consider that when presented with a device that has a significantly different design than a traditional device, decisions regarding preference and future use can be dependent upon the individual practitioner's style and technique. All of these factors can affect the evaluation of safety devices and could account for the variety of opinions obtained during this evaluation. This illustrates the importance of having staff members responsible for patient care involved in the identification and selection process when considering and evaluating new safety devices.

Manufacturer	Septodont, Inc.		
	245 Quigley Blvd		
	New Castle, DE 19720-4105		
	(800) 872-8305		
	(302) 328-5653 FAX		
	www.septodontusa.com		
Suggested Retail Price	\$27.99 100 disposable, siliconized, triple beveled injectors1; 5 replacement		
	silicone tips for the reusable handle; and 1 autoclavable handle		
	\$11.29 Additional autoclavable handle		
Government Price	\$23.79 100 disposable, siliconized, triple beveled injectors1; 5 replacement		
	silicone tips for the reusable handle; and 1 autoclavable handle		
	\$9.60 Additional autoclavable handle		

Advantages <sup>2</sup>	+ Potential to decrease percutaneous injuries compared to conventional syringe system + Provides an engineering control making incorrect needle recapping less likely + Safe and easy breakdown and insertion into sharps container + Adaptable to any hand size + Protective sheath fitted with siliconized, triple beveled needles + Disposable and lightweight
Disadvantages <sup>2</sup>	<ul> <li>Time consuming to change anesthetic carpules</li> <li>May be difficult to see aspirated blood through the protective sheath</li> <li>Lightweight plastic construction may make the device feel unstable</li> <li>Produces an increased volume of sharps waste</li> <li>Requires a certain period of accommodation by the user</li> <li>More expensive than a conventional syringe system</li> </ul>

<sup>&</sup>lt;sup>1</sup>Five needle sizes are available

# **Evaluation of Safety Scapels** (12/04) **UPDATED** (12/07)

**Question:** I recently saw an advertisement for a safety scalpel. Has DECS evaluated any safety scalpels and if so, what are the advantages and disadvantages of using them compared to a reusable scalpel handle with disposable blades?

Answer: DECS completed an evaluation of the Lark Retractable Safety Scalpel (now known as the Futura™ Safety Scalpel) several years ago and recently evaluated the Miltex Disposable Safety Scalpel. Scalpel blades are a type of sharp that have been implicated in percutaneous injuries. With a conventional scalpel, injuries can occur when passing the scalpel between dental health-care personnel (DHCP); when removing the contaminated blade from the handle before disposal; and when the blade is left uncovered on the instrument tray. Both of the disposable safety scalpels evaluated by DECS are designed to protect DHCP from surgical blade injuries. These safety scalpels have a fully retractable blade designed to protect DHCP from accidental percutaneous injuries associated with conventional sterilizable scalpel handles and disposable blades. The operator can easily extend or retract the blade using one hand. Because the blade can be retracted during periods of non-use or during instrument passing, they are potentially safer. Also, the blade does not have to be removed from the handle before disposal. These features can minimize the potential for percutaneous injury and create a safer environment for DHCP. Table 1 provides general information about the Futura™ Safety Scalpel and the Miltex Disposable Safety Scalpel.

While it is not presently mandatory to use safety scalpels, the Occupational Safety and Health Administration (OSHA) requires annual consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure. Both the Miltex and Futura<sup>TM</sup> safety scalpels were found to be safe for clinical use during our limited evaluations, and are examples of devices that could be evaluated in USAF dental clinics to fulfill the OSHA safety device evaluation requirement. It's also important to consider that when presented with a device that has a significantly different design than a traditional device, decisions regarding preference and future use can be dependent upon the individual practitioner's style and technique. There are several other safety scalpels available with engineering controls, and dental clinics are not just limited to evaluating the two safety scalpels that DECS has evaluated.

<sup>&</sup>lt;sup>2</sup>Information compiled from limited DIS clinical evaluations.

Table 1. Summary of Safety Scalpels Evaluated by DECS

	Futura™ Safety Scalpel <sup>¹</sup>	Miltex Disposable Safety Scalpel
Manufacturer  Price	Merit Medical Systems 1600 West Merit Parkway South Jordan, UT 84095 (800) 356-3748 (801) 253-1600 (801) 253-1652 FAX www.merit.com Suggested Retail Price:	Miltex, Inc. 589 Davies Dr. York, PA 17402 (800) 645-8000 (717) 840-9355 (717) 840-9347 FAX www.miltex.com Suggested Retail Price <sup>2</sup> :
	Box of 50 blades \$75.00  Government Price: Box of 50 blades \$50.00	Box of 10 blades \$24.72  Government Price <sup>2</sup> :  Box of 10 blades \$11.65
Available Blade Sizes Summary of Safety Feature	#s 10, 11, 15  Spring-based slider that automatically retracts the blade into the device body when pressed with audible confirmation	#s 10, 11, 15  To retract the blade, the user pushes the slider to the right and back until the blade locks into place
Advantages <sup>3</sup>	+ Potentially safer because it may minimize risk for percutaneous injuries + Potentially safer for patients and staff because blade can remain retracted until needed + Minimal user intervention required to activate safety feature + Conveniently packaged + Lightweight and well balanced + Safety feature is easy to recognize and use + Provides audible confirmation of blade lock + Safety feature can be activated with one hand + Enhances infection control because of its disposability	+ Potentially safer because it may minimize risk for percutaneous injuries + Potentially safer for patients and staff because blade can remain retracted until needed + Conveniently packaged + Lightweight and well balanced + Safety feature is easy to recognize and use + Safety feature can be activated with one hand + Enhances infection control and safety because of its disposability
Disadvantages <sup>3</sup>	Handle is thicker than traditional scalpel handle; may make handling cumbersome     Potential exists for blade to be inadvertently retracted when making incisions	- Blade/handle connection more flexible than a conventional device making the device feel unstable during use -Handle is thicker than traditional scalpel handle; may make handling cumbersome - Potential exists for blade to be inadvertently retracted when making incisions

At the time of the DECS evaluation in 2001, the device was known as the Lark Retractable Safety Scalpel and in 2004 the manufacturer was Hypoguard USA, Inc. The current manufacturer and pricing information as of 12/07 is listed in the table.

Available for purchase through American Medical Depot at (305) 364-0888

<sup>&</sup>lt;sup>3</sup> Information compiled from limited DECS clinical evaluations.

**Safety Intravenous (IV) Catheters as an Infection Control Tool** (Originally published in the May 2001 issue of InCONTROL)

Question: Are safety intravenous (IV) catheters a good idea for our dental clinic?

**Answer:** Any sharp device can result in a percutaneous injury, but not all devices carry the same risk of bloodborne pathogen transmission. Those most likely to transmit diseases are blood-filled needles used for vascular access. Disposable needles are involved in more injuries than other devices, but rank third among devices causing high-risk injuries. The reason is because these devices are most often used to give injections (low-risk procedure) and not to withdraw blood.

The IV catheter stylet ranks first among blood-filled devices causing high-risk injuries. Studies have shown that safety IV catheters can significantly reduce injury rates. These devices provide a protective shield for the stylet before or during its withdrawal from the catheter. It is recommended that these devices be used in all healthcare facilities as soon as possible.